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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,499

10/28/2003

Vincenzo Scarlato

2300-0363.01

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27476

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11/07/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/695,499

**Applicant(s)**

SCARLATO ET AL.

**Examiner**

Jennifer E. Graser

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2, 3, 8, 10, 13, 18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 3, 8, 18, 20 and 21 is/are allowed.
- 6) ☒ Claim(s) 10 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/8/08 has been entered.

Claims 2, 3, 8, 10, 13, 18, 20 and 21 are currently under examination.

### ***Claim Objections***

2. Claims 10 and 13, objected to because of the following informalities:

The claims spell 'hybridize' and 'hybridization' with an 's'. The claims of this US Patent Application should reflect the American English spelling. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

3. Claims 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears that the claimed nucleic acid would be detecting N.meningitidis **DNA** through hybridization, not the bacterium per se, as recited in the claims. Appropriate correction is required.

Claim 10 is vague and indefinite due to the phrase through 'hybridisation'. The claims do not recite any hybridization conditions. Hybridization conditions can vary considerably. A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration and salt concentration. Changes in these parameters will affect the specificity of the binding. Thus, in order to ascertain the metes and bounds of the patent protection, the skilled artisan would require a knowledge of these specific parameters. The claim does not clearly and unambiguously set forth the appropriate reaction conditions. The rejection may be overcome by clearly setting forth the reaction conditions encompassed by a stringent hybridization, as supported by the disclosure.

***Allowable Subject Matter***

4. Claims 2, 3, 8, 18 and 21 will be allowed, pending the outcome of an updated interference search. Claims 10 and 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Applicants previously showed that Peak et al (US Patent No. 6,197,312) does not qualify as prior art. Additionally, the instant claims are drawn to nucleic acid and not proteins like the claims of Peak '312 and would not present an interference issue. A previous interference search did not reveal any pending claims drawn to interfering subject matter, e.g., claims to similar nucleic acid.

5. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/  
Primary Examiner, Art Unit 1645

11/5/08